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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/975,143 | 10/10/2001 | Daniel K. Hsu | DANHSU.001C1 | 8888 |
| 7590 | 06/15/2005 | | EXAMINER | |
| DANIEL K. HSU 2624 BELLOWS ST. DAVIS, CA 95616-7656 | | | AEDER, SEAN E | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1642 | |

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/975,143 | HSU ET AL. | |
| | Examiner | Art Unit | |
| | Sean E. Aeder, Ph.D. | 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-29 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, drawn to a method of identifying the presence of galectin-3 in cirrhotic or cancerous liver with an antibody, classified in class 435, subclass 7.1.
- II. Claims 4-9, drawn to a method of identifying the amount of galectin-3 expression in cirrhotic or cancerous liver, classified in class 435, subclass 6.
- III. Claims 10-16, 20-23, and 28-29, a method of identifying a subject in need of treatment or prevention of liver disease as specifically drawn to probing for gal-3 RNA/mRNA, classified in class 435, subclass 7.21.
- IV. Claims 10-15, 20-23, 24-27 a method of identifying a subject in need of treatment or prevention of liver disease as specifically drawn to probing for gal-3 protein, classified in class 435, subclass 4.

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V. Claims 17 (in part) and 19 (in part), drawn to a method of making a pharmaceutical for the treatment or prevention of hepatocellular carcinoma, classified in class 514, subclass 1.

(Upon election of group II, Applicant must elect a single agent from those listed in claims 17 and 19 as each agent encompasses a distinct invention, not a species.)

VI. Claims 18 (in part) and 19 (in part), drawn to a method of treatment for hepatocellular carcinoma or cirrhosis of the liver comprising administering an agent which inhibits production of galectin-3 in liver cells or tissue in a pharmaceutical formulation, classified in class 424, subclass 193.1.

(Upon election of group III, Applicant must elect a single agent from those listed in claims 18 and 19 as each agent encompasses a distinct invention, not a species.)

The inventions are distinct, each from the other because of the following reasons:

The inventions of groups I-VI are materially distinct methods. Group I is drawn to a method of identifying the presence of gal-3, group II is drawn to identifying the amount of gal-3, group III is drawn to probing for RNA or mRNA to identify a subject in need of treatment, group IV is drawn to probing for protein to identify a subject in need of treatment, group V is drawn to making a pharmaceutical, while group VI is drawn to a method of treatment. These inventions differ at least in objectives, method steps,

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reagents and/or dosages and/or schedules used, response variables, and criteria for success. Furthermore, the search and examination of groups I-VI would result in a burdensome search because extensive searching would be required to examine the various method steps and reagents involved with each invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Species

Claims 6, 13 are generic to a plurality of disclosed patentably distinct species comprising the following: nucleic acids, proteins, carbohydrate chemical agents, and peptidomimetics. The products of the above species represent separate and distinct molecules with different structures and functions such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

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case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA


GARY B. NICKOL, PH.D.
PRIMARY EXAMINER